PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
GOLDENBERG
Serial No.: 10/314,330
Filed: December 9, 2002
Title: IMMUNOTHERAPY OF B-CELL MALIGNANCIES USING ANTI-CD22 ANTIBODIES
Group Art Unit: 1643
Examiner: Alana M. Harris
Attorney Docket No.: IMMU:007US4

EFS-WEB

DECLARATION UNDER 37 CFR § 1.132

MAIL STOP AMENDMENT
COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

Sir:

I, John Leonard, being duly warned, declare as follows:

1. I am the Clinical Director at the Cornell Center for Lymphoma and Myeloma at the New York-Presbyterian Hospital. I have an extensive background in the field of immunotherapy for cancer treatment, as evidenced by my Curriculum Vitae, which is attached. I have been a key investigator on clinical trials relating to immunotherapy of various B-cell malignancies, particularly rituximab. For example, I am currently a principal investigator for a phase II trial that is studying rituximab versus lenalidomide versus rituximab + lenalidomide in recurrent follicular Non-Hodgkin Lymphoma (NHL) after relapse from a rituximab-containing combination regimen.

2. I am familiar with the article Maloney *et al.*, *Blood*, 84(8): 2457-2466 (1994). This article relates to results from a Phase I clinical trial to evaluate the safety of anti-CD20 antibody as a single agent therapeutic.

3. Maloney 1994 states, on page 2465, that "extension of these studies to patients with minimal disease, using antibody alone or in combination with conventional therapies, may provide the greatest benefit. The disclosure in Maloney that anti-CD20 may be combined with a

"conventional therapy" would not have suggested to me therapy with a combination of an anti-CD20 antibody and another antibody, such as an anti-CD22 antibody. This is because "conventional therapies" at the time of the Maloney article, circa 1994, were chemotherapies, not antibody therapies.

4. "Conventional" means "conforming to established practice or accepted standards; traditional" (The American Heritage® Dictionary of the English Language: Fourth Edition - 2000). An investigational drug in Phase I clinical trials cannot be considered a conventional therapy, *i.e.*, it does not conform to established practice or accepted standards." By definition, investigational drugs have not been "accepted." Companies can provide investigational drugs to doctors if they are part of a drug trial covered by an FDA-approved protocol, and such drugs are by definition not conventional, since they are not available for use by any doctor on any patient.

5. In 1994 (and later) antibody therapies were not "conventional," and therefore Maloney's comment regarding the addition of "conventional therapies" to his anti-CD20 antibody suggests to a skilled clinician a combination of the anti-CD20 single antibody therapy with a chemotherapy. It would not have suggested therapy with a combination of antibodies. "Conventional therapies," circa 1994 and later, were chemotherapies. The first approved antibody for therapy of any malignancy was the anti-CD20 antibody rituximab that is the subject of Maloney, but it was not approved until 1997, and therefore there was no cancer therapy with any antibody that was a conventional therapy in 1994.

6. Treatment with anti-CD22 antibody was not conventional circa 1994. For example, Goldenberg *et al.*, *J. Clin. Oncol.*, 9: 548-564 (1991) relates to results from a pilot Phase I study involving a small number of patients to see the feasibility of giving this radiolabeled antibody, involving targeting tumor and organs, doses delivered to tumor and normal organs, and any evidence of efficacy in a small number of patients, and does not establish that treatment with anti-CD22 antibody was "conventional." Juweid *et al. Cancer Res.*, 55:5899s-5907s (1995) is a follow-on report of further treatment of patients with low doses and initial results of high dose therapy in a Phase I trial. Here again, these were early investigational studies and do not represent conventional therapy.

7. Current reviews and texts support the fact that antibody therapy using a combination of antibodies to different targets is not conventional. No such combination therapy has been approved, and even combinations of rituximab with conventional chemotherapy for lymphoma have only been approved by the FDA within the past two years. Although some articles began to discuss

the possibility of combination antibody therapies following publication by Immunomedics of their studies of epratuzumab and rituximab in about 2002/2003, none of these indicate that such therapy is "conventional." For example, "What is New in Lymphoma," published in 2004, cites rituximab as an advancement in the treatment of NHL. Cheson, CA *Cancer J Clin*, Sep-Oct; 54(5):260-72 (2004). Efforts to improve the activity of rituximab are noted, and include increasing the number of weekly infusions, delivering higher doses and increasing dose density. Combinations with CHOP are also mentioned. The Cheson article also references both a Phase II study of a combination of rituximab with epratuzumab and a phase I/II study of the combination of galiximab and rituximab, each of which were reported in 2003, demonstrating that combination antibody therapy was still very much investigational at this later date.

9. Currently I am principal investigator of a phase II study of combination antibody therapy, in this case rituximab plus galiximab (anti-CD80) (currently in press for publication in *Annals of Oncology*). I would not have understood Maloney 1994 to have suggested such a combination antibody therapy based on the statement in the article that "extension of these studies to patients with minimal disease, using antibody alone or in combination with ***conventional therapies***, may provide the greatest benefit." I would have understood Maloney's statement to suggest combinations of the anti-CD20 antibody with chemotherapy, which was "conventional" in 1994. Even single antibody therapy was not conventional in 1994.

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I hereby declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

3/12/07
Date

John P. Leonard, MD

CURRICULUM VITAE

Name: John P. Leonard, M.D.

Date of preparation: January 4, 2007

A. GENERAL INFORMATION

Office address:	Starr Building, Room 340 Division of Hematology/Oncology Weill Medical College of Cornell University 520 East 70th Street New York, NY 10021
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Citizenship:	USA

Optional information

Birth date:	June 13, 1965
Birth place:	Virginia
Social Security Number:	Upon request
Marital status:	Married
Spouse's name:	Leah Smith Leonard
Children's name and ages:	Madeline (10), Abigail (7), Zachary (5)
Race/Ethnicity:	Caucasian

B. EDUCATIONAL BACKGROUND

Degree	*Institution name, city and state*	*Dates attended*	*Year Awarded*
B.A.	Johns Hopkins University Baltimore, Maryland	1982-1986	1986
M.D.	University of Virginia Charlottesville, Virginia	1986-1990	1990

C. PROFESSIONAL POSITIONS AND EMPLOYMENT

Post-doctoral training including residency/fellowship

Title	*Institution name, city and state*	*Dates*
Intern, Resident, Assistant Chief Resident	Department of Medicine New York Hospital-Cornell Medical Center, New York, New York Memorial Sloan-Kettering Cancer Center, New York, New York	1990-1993
Fellow, Chief Fellow	Division of Hematology-Oncology New York Hospital – Cornell Medical Center, New York, New York	1993-1996

Academic positions (teaching and research)

Title	*Institution name, city and state*	*Dates*
Instructor in Medicine	Division of Hematology-Oncology Department of Medicine Weill Medical College of Cornell University	1995-1996
Chief Resident	Department of Medicine New York Hospital – Cornell Medical Center, New York, New York	1996-1997
Senior Clinical Associate in Medicine	Department of Medicine Weill Medical College of Cornell University, New York, New York	1996-1997
Assistant Professor of Medicine	Division of Hematology-Oncology Department of Medicine Weill Medical College of Cornell University, New York, New York	1997-2004
Associate Professor of Medicine	Division of Hematology-Oncology Department of Medicine Weill Medical College of Cornell University, New York, New York	2004-present

Hospital positions (attending physician)

Title		*Institution name, city and state*	*Dates*
Assistant Physician	Attending	New York Weill Cornell Medical Center New York Presbyterian Hospital New York, New York	1995-2004
Associate Physician	Attending	New York Weill Cornell Medical Center New York Presbyterian Hospital New York, New York	2004-present

Employment (other than positions listed above)

N/A

D. LICENSURE, BOARD CERTIFICATION, MALPRACTICE (if applicable)

Licensure

State	*Number*	*Date of Issue*	*Date of last registration*
New York	186477	1991	2006

DEA number: BL 3656541

Board Certification

Name of specialty	*Board Certificate #*	*Date of Certification*
Internal Medicine	148759	1993
Hematology	148759	1996, 2006
Medical Oncology	148759	1997, pending

Malpractice insurance

Do you have Malpractice insurance? Yes

Name of Provider: MCIC Vermont (through Weill Cornell)

Premiums paid by: *(self/ group/ institution (give name of group/institution)*
Weill Medical College of Cornell University

E. PROFESSIONAL MEMBERSHIPS (*medical and scientific societies*)

Member/officer	*Name of Organization*	*Dates held*
Member	American College of Physicians	1993
Member	American Federation for Medical Research	1993
Member	American Society of Hematology	1994
Member	American Society of Clinical Oncology	1997
Member	Cancer and Leukemia Group B	2000
Member	New York Cancer Society	2001

F. HONORS AND AWARDS

Name of award	*Date awarded*
Raven Society, University of Virginia	1989
Medical Alumni Association Outstanding Medical Student Award, University of Virginia School of Medicine	1990
Medical Housestaff Program Director's Award, Department of Medicine, New York Hospital – Cornell Medical Center	1993
Chief Medical Resident, Department of Medicine, New York Hospital – Cornell Medical Center	1996
Mentored Patient-Oriented Research Career Development Award (K23), National Institutes of Health	2001
First Prize, Department of Medicine Investigator Award, Weill Medical College of Cornell University	2005

G. INSTITUTIONAL/HOSPITAL AFFILIATION

Primary Hospital Affiliation:	New York Weill Cornell Medical Center New York Presbyterian Hospital New York, New York
Other Hospital Affiliations:	N/A
Other Institutional Affiliations:	N/A

H. EMPLOYMENT STATUS

Name of Employer(s): Weill Medical College of Cornell University

Employment Status: Full-time salaried by Weill Cornell

I. CURRENT AND PAST INSTITUTIONAL RESPONSIBILITIES AND PERCENT EFFORT

Teaching	Dates
Chief Medical Resident, Department of Medicine	1996-1997
Ward teaching attending, 2-4 months/year (3 hrs/day teaching rounds with students, fellows and housestaff while attending on service)	1997-present
Laboratory session instructor for medical students including Basis of Disease course (Lymphoma laboratory, 2 hours/year)	1997-present
Hematology/Oncology lectures to medical students and housestaff (4 informal lectures/year to students/housestaff on "lymphoma basics", generally 1 formal lecture/year on "Non-Hodgkin's Lymphoma)	1997-present
Hematology/Oncology lectures to fellows (1-2/year on "Indolent lymphoma" and "Aggressive lymphoma")	1997-present
Morning report teaching attending, Department of Medicine (1-2 weeks/year)	1997-present
Hematology/Oncology Lymphoma Clinic attending (supervising fellows and rotating residents/students – generally 10-15 hours/week)	2000-present
Research mentor for trainees	2001-present

Fellows

Richard Furman, M.D. – currently Assistant Professor of Medicine, Weill Medical College of Cornell University

Alan Dosik, M.D. – currently Attending Physician, New York Methodist Hospital

Abby Siegel, M.D. – currently Assistant Professor of Medicine, Columbia University College of Physicians and Surgeons

Jia Ruan, M.D. – currently Assistant Professor of Medicine, Weill Medical College of Cornell University

Biree Andemariam, M.D. – current 3rd year fellow

Medical Residents
Geoffrey Ku, M.D.
Jody Mones, M.D.

Medical Students
Elena Schoenberger
Sarah Rutherford

Course Director (medical students), Malignant Hematology (4^{th} year elective rotation, approximately 5 students/year)	2003-present
Director, Hematology-Oncology Fellowship Program (3 fellows/year)	2003-2005

Clinical Care	Dates
Ward attending (2-4 months/year) and Lymphoma clinic (outpatient) attending (2 days/week)	1997-present

Administrative duties	Dates
Housestaff Committee, Department of Medicine, New York Hospital – Cornell Medical Center	1990-1993, 1996-1997
Intern Selection Committee, Department of Medicine, New York Weill Cornell Medical Center	1993-present
Cardiac Arrest Committee, New York Hospital – Cornell Medical Center	1996-1997
Task Force on Patient Restraints, New York Hospital – Cornell Medical Center	1996-1997
Quality Assurance Committee, Department of Medicine, New York Weill Cornell Medical Center	1996-1997, 1998-2005
Oncology Cluster Committee (Medical Director), New York Weill Cornell Medical Center	1997-2001
Director, Inpatient Oncology Unit, New York Weill Cornell Medical Center	1997-2003
Medical Director, Oncology Services, New York Weill Cornell Medical Center	1999-2003
Clinical Director, New York-Cornell Center for Lymphoma and Myeloma	1998-present

Hematology/Oncology Subcommittee, Formulary and Therapeutics Committee, New York Presbyterian Hospital	2000-2003
Oncology Operations Council/Bicampus Cancer Council, New York Weill Cornell Medical Center	2001-present
Clinical Protocol Review Committee, Division of Hematology-Oncology, Weill Medical College of Cornell University (Chair, 2005-present)	2001-present
Radiation Safety Committee, New York Weill Cornell Medical Center	2002-present
Director, Hematology-Oncology Fellowship Program, New York Weill Cornell Medical Center (responsible for training, clinical and research activities of 3 fellows/year)	2003-2005
Associate Director, Clinical Research Program, Division of Hematology/Oncology	2004-2005
Director, Clinical Research Program, Division of Hematology/Oncology (supervise clinical trials office, responsible for management of 35+ staff and average of 80+ ongoing trials and 400+ patient accruals/year, funded through National Cancer Institute, foundation, industry and institutional support)	2005-present
Director of Clinical Research Development, Institute for Clinical Research, Weill Medical College of Cornell University (collaborate with ICR leadership to focus on development of new programs to enhance the quality and extent of clinical and translational research programs at Weill Cornell)	2006-present

<u>Research</u>	<u>Dates</u>
Regulation of hematopoiesis, Division of Experimental Hematology, Johns Hopkins Oncology Center (Johns Hopkins School of Medicine), Saul Sharkis, PhD	1984-1990

Gene therapy in hematopoietic cells, Laboratory of Developmental Hematopoiesis (Sloan Kettering Institute), Malcolm A.S. Moore, D Phil	1994-1996
Immunotherapy, radioimmunotherapy, chemotherapy and other novel therapeutic approaches for non-Hodgkin's lymphoma and Hodgkin's disease	1997-present
New imaging modalities for lymphoma	1997-present
Member, Lymphoma Core Committee, Cancer and Leukemia Group B, National Cancer Institute	1998-present
Leader, Non-Hodgkin's Lymphoma Working Group, Lymphoma Core Committee, Cancer and Leukemia Group B, National Cancer Institute (work with other committee leadership to establish the portfolio of clinical and translational research in lymphoma in CALGB, a cooperative group of the NCI with 25+ academic main member institutions nationally)	2003-present
Principal Investigator (Weill Medical College of Cornell University), Cancer and Leukemia Group B (Main Member Institution), National Cancer Institute	2006-present
Principal Investigator (Weill Medical College of Cornell University site) and Executive Committee, New York Cancer Consortium, National Cancer Institute (one of 8 phase II cancer consortia of the NCI nationally)	2006-present

Check if activity involves WMC

Current percent effort	*%*	*students*	*researchers*
Teaching	5%	x	x
Clinical Care	45%	x	x
Administration	20%	x	x
Research	30%	x	x
Total	100%		

J. RESEARCH SUPPORT (past and present)

NIH, peer-reviewed, investigator-initiated:

K23 - RR16814, Mentored Patient-Oriented Research Career Development Award, "Novel monoclonal antibody therapies for lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
National Institutes of Health, National Center for Research Resources	$540,000	9/1/01-8/31/06	John P. Leonard

Individual's role in project including percent effort
Principal investigator (75% effort)

UO1 – HL72196, "Novel therapies in hemostasis and transfusion medicine"

Source	*Amount*	*Date*	*Name of Principal Investigator*
National Institutes of Health – National Heart, Lung, Blood Institute		2002-2007	James B. Bussel

Individual's role in project including percent effort
Co-investigator (5% effort)

U10 –CA31946, "Cancer and Leukemia Group B"(subcontract), CALGB Foundation, and Clinical Trials Support Unit (CTSU)

Source	*Amount*	*Date*	*Name of Principal Investigator*
National Institutes of Health, National Cancer Institute	$123,850 (2005-6)	2005-2009	Richard L. Schilsky

Individual's role in project including percent effort
Principal investigator, Main Member Institution (New York Weill Cornell)

N01- CM-17103 - NCI Phase II contract, "Early therapeutics development with phase II emphasis, New York Cancer Consortium"(subcontract)

Source	*Amount*	*Date*	*Name of Principal Investigator*
National Institutes of Health, National Cancer Institute	$338,300 (2005-6)	2005-2010	Joseph Sparano

Individual's role in project including percent effort
Principal investigator (New York Weill Cornell Site) and Member, Executive Committee

R21 – CA126060 , Quick-Trials for Novel Cancer Therapies, "CD74-directed immunotherapy for B cell malignancies" (Anticipated award – Priority score 128, 2.6 percentile with current payline 8%)

Source	*Amount*	*Date*	*Name of Principal Investigator*
National Institutes of Health, National Cancer Institute	$521,093 direct costs	2007-2009	John P. Leonard

Individual's role in project including percent effort
Principal investigator (25% effort)

Foundation or institutional, peer-reviewed, investigator-initiated

Pilot Grant in Aging Research, "Monoclonal antibody-based immunotherapy in older patients with non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Cornell Center for Aging Research and Clinical	$20,000	2002-2003	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

Research grant, "Clinical, pathologic and molecular correlative studies in lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Dorothy Rodbell Cohen Foundation	$50,000	2003-2004	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

Mantle cell lymphoma research grant ("R01 type"), "Angiogenesis and anti-angiogenic therapy in mantle cell lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Lymphoma Research Foundation	$950,000	2003-2007	John P. Leonard

Individual's role in project including percent effort
Principal investigator (10% effort)

Research grant, "Monoclonal antibody-based therapies for B cell malignancies"

Source	*Amount*	*Date*	*Name of Principal Investigator*
The Lymphoma Foundation	$30,000	2005-2007	John P. Leonard

Individual's role in project including percent effort
Principal investigator (10% effort)

Pending foundation or institutional, peer-reviewed, investigator-initiated

CLL/SLL research grant ("R01 type"), "CD74-directed therapy of CLL/SLL"

Source		*Amount*	*Date*	*Name of Principal Investigator*
Lymphoma Foundation	Research	$750,000 direct costs	Pending; 2007-2010	John P. Leonard

Individual's role in project including percent effort
Principal investigator (5% effort)

Mantle cell lymphoma research grant ("R01 type"), "Annexin 2 in Mantle Cell Lymphoma Angiogenesis"

Source		*Amount*	*Date*	*Name of Principal Investigator*
Lymphoma Foundation	Research	$663,177 direct costs	Pending; 2007-2010	Katherine A. Hajjar

Individual's role in project including percent effort
Co-investigator (5% effort)

Industry-sponsored, investigator-initiated clinical trials

"Multicenter, pivotal phase III study of Iodine-131 anti-B1 antibody (murine) radioimmunotherapy for chemotherapy-refractory low-grade B-cell lymphomas and low-grade B-cell lymphomas that have transformed to higher grade histologies"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Corixa Corporation	$5,150	1998-ongoing	Stanley J. Goldsmith

Individual's role in project including percent effort
Co-investigator (<5% effort)

"A randomized study of Iodine-131 anti-B1 antibody versus anti-B1 antibody in chemotherapy-relapsed/refractory low-grade of transformed low-grade non-Hodgkin's lymphoma (NHL)"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Corixa Corporation	$336,468	1999-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Retreatment study of patients with non-Hodgkin's lymphoma who have previously responded to Iodine-131 antibody"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Corixa Corporation	$8,000	1998-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Fludarabine monophosphate followed by Iodine-131 anti-B1 antibody for untreated low-grade and follicular non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Corixa Corporation	$165,331	1998-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Phase I/II clinical trial of immunotherapy with Mab hLL2 in patients with recurrent non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Immunomedics, Inc	$369,055	1998-ongong	John P. Leonard
Amgen, Inc		1998-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Expanded access study of Iodine-131 anti-B1 antibody for relapsed/refractory low-grade and transformed low-grade NHL"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Corixa Corporation	$166,125	1999-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Phase I, dose-escalation study of Iodine-131 anti-B1 antibody for patients with previously treated non-Hodgkin's lymphoma with more than 25% bone marrow involvement"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Corixa Corporation	$53,000	1999-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Data management support grant"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Corixa Corporation		1999-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Phase I trial of humanized 1D10 monoclonal antibody (Hu1D10) in patients with relapsed non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Protein Design Labs		1999-2000	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Phase II multicenter study of Iodine-131 anti-B1 antibody consolidation for patients with diffuse large B-cell non-Hodgkin's lymphoma following first-line CHOP"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Corixa Corporation	$23,500	2000-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Phase II multicenter study of CVP followed by Iodine-131 anti-B1 antibody for patients with untreated low-grade non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Corixa Corporation	$81,057	2000-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"A phase II trial of immunotherapy with humanized LL2 (epratuzumab) in combination with rituximab in patients with refractory or recurrent non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Immunomedics, Inc., and Amgen, Inc.	$129.131	2000-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"A phase III trial evaluating the safety and efficacy of specific immunotherapy, recombinant idiotype conjugated to KLH with GM-CSF, in patients with follicular non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Genitope Corporation	$229,406	2000-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"A phase II trial to evaluate the rate of immune response using idiotype immunotherapies produced by molecular biological means for treatment of aggressive B-cell lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Genitope Corporation	$49,850	2000-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"A phase III clinical trial of immunotherapy with humanized LL2 IgG (AMG 412) in subjects with low-grade, follicular, B-cell non-Hodgkin's lymphoma refractory to rituximab"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Amgen, Inc.	$44,197	2000-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Randomized study of fludarabine and cyclophosphamide with or without Bcl-2 antisense oligonucleotide in patients with relapsed or refractory chronic lymphocytic leukemia"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Genta, Inc.	$12,500	2002-2005	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"A randomized phase III multicenter controlled clinical trial to evaluate the efficacy and safety of IDEC-Y2B8 radioimmunotherapy compared to rituximab immunotherapy of relapsed or refractory low-grade or follicular B-cell non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Idec Pharmaceuticals		1999-2001	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"A phase II clinical trial testing AMG 412 (anti-CD22, epratuzumab) in combination with rituximab in rituximab-naïve patients with refractory or recurrent low-grade CD20+ B-cell non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Amgen, Inc.	$30,400	2002-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Phase II study of FavId (tumor-specific idiotype-KLH) and soluble GM-CSF immunotherapy in patients with stable or progressive low-grade follicular B-cell lymphomas"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Favrille, Inc.	$20,840	2002-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Phase II open label, randomized, dose and schedule finding, clinical trial of immunotherapy with AMG 412 (epratuzumab, anti-CD22) in subjects with diffuse large B-cell non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Amgen, Inc.	$9,900	2002-2003	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

A phase I/II trial of anti-CD80 monoclonal antibody (IDEC-114) therapy for patients with relapsed or refractory follicular lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Idec Pharmaceuticals	$34,000	2002-2006	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Multicenter, phase I, open label, two arm, non-randomized, dose-escalation study of the safety and tolerability of CpG 7909 in patients receiving rituximab for relapsed or refractory B-cell non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Coley Pharmaceuticals	$82,045	2002-2006	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Multicenter study of Bcl-2 antisense alone or in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone (R-CHOP) in patients with newly diagnosed, refractory or relapsed mantle cell lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Genta, Inc.	$148,000	2002-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Open label phase II/III study of rituximab in combination with recombinant human IL-2 for relapsed low-grade or follicular non-Hodgkin's lymphoma in subjects who have previously failed rituximab"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Chiron, Inc.	$30,720	2002-2005	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Phase I/II multi-dose study of SGN-30 (anti-CD30) in patients with refractory or recurrent CD30+ hematologic malignancies"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Seattle Genetics, Inc.	$36,042	2002-2006	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Phase II study of intravenous T900607-sodium in subjects with previously treated non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Tularik, Inc.	$8,400	2002-2003	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Phase I/II trial of IDEC-114 (anti-CD80 monoclonal antibody) in combination with rituximab for patients with relapsed or refractory follicular lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Idec Pharmaceuticals	$116,241	2002-2006	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"A phase II multicenter study of gallium nitrate in patients with refractory non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Genta, Inc.	$46,550	2002-2005	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"A phase II study to evaluate safety and efficacy of specific immunotherapy, recombinant idiotype conjugated to KLH and GM-CSF following the anti-CD20 antibody rituximab in previously treated patients with follicular non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Genitope, Inc.	$100,444	2003-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"A phase II study of Yttrium-90 labeled ibritumomab tiuxetan and rituximab in relapsed diffuse large B-cell lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Idec Pharmaceuticals	$49,500	2003-2006	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Phase I/II trial of bortezomib (PS-341) and CHOP-rituximab in previously untreated diffuse large B-cell lymphoma and mantle cell lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Millenium Pharmaceuticals	$261,000	2003-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"A phase 2 study of Velcade (bortezomib) in subjects with relapsed or refractory mantle cell lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Millenium Pharmaceuticals	$36,759	2003-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"A phase II multi-dose study of SGN-30 (anti-CD30 mAb) in patients with refractory or recurrent Hodgkin's disease or anaplastic large cell lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Seattle Genetics	$54,865	2003-2006	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"A phase I study of immunotherapy with hA20 administered once weekly for 4 consecutive weeks in patients with low-grade, follicular non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Immunomedics	$68,105	2004-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Phase II trial of anti-angiogenic therapy with RT-PEP-C in patients with relapsed mantle cell lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Lymphoma Research Foundation		2004-ongoing	John P. Leonard

Individual's role in project including percent effort
Co-principal investigator (<5% effort)

"Intravenous administration of SB-743921 on days 1 and 15 of a 28-day cycle in non-Hodgkin's lymphoma"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Cytokinetics, Inc		2006-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"Single-agent AT-101 in relapsed or refractory B-cell malignancies"

Source	*Amount*	*Date*	*Name of Principal Investigator*
Ascenta, Inc.	$4,958	2006-ongoing	John P. Leonard

Individual's role in project including percent effort
Principal investigator (<5% effort)

"CALGB 50401 – A randomized phase II trial of rituximab vs. lenalidomide (Revlimid™, CC-5013) (IND#73034) vs. rituximab _ lenalidomide in recurrent follicular non-Hodgkin's lymphoma (NHL) after relapse from a rituximab-containing regimen"

Source	*Amount*	*Date*	*Name of Principal Investigator*
CALGB		2006-ongoing	John P. Leonard

Individual's role in project including percent effort
Overall National Principal investigator (<5% effort)

K. EXTRAMURAL PROFESSIONAL RESPONSIBILITIES

Reviewer for *Annals of Internal Medicine*	1998-
Reviewer for *Cancer*	1998-
Reviewer for *Cancer Investigation*	1998-
Member, Lymphoma Core Committee, Cancer and Leukemia Group B (CALGB), National Cancer Institute	2000-
Member, Medical Affiliates Board, Lymphoma Research Foundation	2001-
Reviewer, *Leukemia and Lymphoma*	2002-
Reviewer, *Blood*	2002-
Member, Editorial Board, *Clinical Lymphoma*	2002-
Abstract Reviewer, American Society of Hematology Annual Meeting	2002
Co-chairman, Lymphoma/Myeloma 2002 (international meeting), New York, NY	2002
Member, Public Policy Committee, Lymphoma Research Foundation	2003 -

Member, Editorial Board, *Journal of Clinical Oncology*	2003-2005
Coordinating Abstract Reviewer, American Society of Hematology Annual Meeting	2003
Leader, Non-Hodgkin's Lymphoma Working Group, Lymphoma Core Committee, Cancer and Leukemia Group B (CALGB), National Cancer Institute	2003
Member, Scientific Advisory Board, Lymphoma Research Foundation (International foundation dedicated to improvement in treatment and support for patients with lymphoma)	2003
Co-chairman, Lymphoma/Myeloma 2004 (international meeting – 600 participants), New York, NY	2004
Reviewer, Translational Research program, Leukemia and Lymphoma Society (International foundation dedicated to improvement in treatment and support for patients with leukemia, lymphoma and myeloma)	2004-
Member, expert panel of advisors for strategic planning, Leukemia and Lymphoma Society	2005
Member, Executive Committee, Mantle Cell Consortium, Lymphoma Research Foundation	2005-
External Reviewer, Cancer Therapy and Evaluation Program, National Cancer Institute	2005-
Member, Government Affairs Committee, American Society of Hematology	2005-
Member, Board of Directors, Lymphoma Foundation	2005-
Abstract Reviewer, American Society of Hematology	2006

Co-chairman, Lymphoma/Myeloma 2006 (international meeting – 800 participants), New York, NY	2006
Member, Board of Directors, National Coalition for Cancer Research	2007-
Member, Editorial Board, *Blood*	2007-

L. BIBLIOGRAPHY

Publications (Peer-Reviewed)

1. **Leonard JP**, May WS, Ihle JN, Pettit GR, Sharkis SJ. Regulation of hematopoiesis IV: The role of interleukin-3 and bryostatin in the growth of erythropoietic progenitors from normal and anemic W/W^{V} mice. Blood, 1988;72:1492-1496.

2. Sharkis SJ, **Leonard JP**, Ihle JN, May WS. The effects of interleukin-3, bryostatin and thymocytes on erythropoiesis. NY Acad Sci,1989;554:59-65.

3. Moore MAS, **Leonard JP**, Flasshove M, Bertino J, Gallardo H, Sadelain M. Gene therapy - the challenge for the future. Ann Oncol,1996;7(S2):53-58.

4. Flasshove M, Banerjee D, **Leonard JP**, Mineishi S, Li M.-X, Bertino JR. and Moore MAS. Retroviral transduction of human CD34+ umbilical cord blood progenitor cells with a mutated dihydrofolate reductase cDNA. Hum Gene Ther, 1998;9:63-71.

5. Coleman M. Kauffmann T, Nisce LZ, **Leonard JP**. Treatment of non-laparotomized (clinical) stage I and II Hodgkin's disease patients by extended field and splenic irradiation. Int J Rad Oncol Biol Phys, 2000;46:1235-1238.

6. Flasshove M, **Leonard JP**, Bardenheuer W, Moore MAS. Increased resistance and selection in paclitaxel for peripheral blood progenitor cells following transduction with the MDR1 gene. TumorDiagnostik and Therapie (German), 2000;21:51-58.

7. Coleman M, **Leonard JP**, Schuster MW, Kaufman TP. DICE (dexamethasone, ifosfamide, cisplatin, etoposide) infusional chemotherapy for refractory or relapsed non-Hodgkin's lymphoma. Eur J Haematol 2001;66(S1):41-45.

8. **Leonard JP**, Schattner EJ, Coleman M. Biology and treatment of mantle cell lymphoma, Curr Opin Oncol, 2001;13:342-347.

9. Kaminski MS, Zelenetz AD, Press OW, Saleh M, **Leonard JP,** Fehrenbacher L, Lister TA, Stagg RJ, Tidmarsh GF, Knox SJ, Vose JM. Pivotal study of Bexxar™ (Iodine I 131 Tositumomab) for chemotherapy-refractory low-grade or transformed low-grade B-cell non-Hodgkin's lymphomas, J Clin Oncol, 2001;19(19):3918-3928.

10. Press OW, **Leonard JP**, Coiffier B, Levy R, Timmerman J. Immunotherapy of Non-Hodgkin's Lymphomas, Hematology (Am Soc Hematol Educ Program), 2001:221-240.

11. **Leonard JP** and Link BK. Immunotherapy of NHL with Epratuzumab (anti-CD22) and Hu1D10, Semin Oncol, 2002;29(1S2):81-86.

12. Kostakoglu L, **Leonard JP,** Kuji I, Coleman M, Vallabhajosula S, Goldsmith SJ Comparison of fluorine-18 fluorodeoxyglucose positron emission tomography and Ga-67 scintigraphy in evaluation of lymphoma, Cancer, 2002;94(4):879-888.

13. Coleman M, **Leonard J**, Lyons L, Pekle K, Nahum K, Pearse R, Niesvizky R and Michaeli J. BLT-D (clarithromycin [biaxin], low-dose thalidomide, and dexamethasone) for the treatment of myeloma and Waldenstrom's macroglobulinemia, Leuk Lymph, 2002;43(9):1777-1782.

14. Kostakoglu L, Coleman M, **Leonard JP**, Kuji I, Zoe H, Goldsmith SJ. PET predicts prognosis after one cycle of chemotherapy in aggressive lymphoma and Hodgkin's disease, J Nucl Med, 2002;43(8):1018-1027.

15. Coleman M, **Leonard J**, Lyons L, Szelenyi H, Niesvizky R. Treatment of Waldenstrom's macroglobulinemia with clarithromycin, low-dose thalidomide, and dexamethasone. Semin Oncol, 2003;30(2):270-274.

16. **Leonard JP**, Siegel JA, Goldsmith SJ. Comparative physical and pharmacologic characteristics of iodine-131 and yttrium-90: Implications for radioimmunotherapy for patients with non-Hodgkin's lymphoma, Cancer Invest, 2003;21(2):241-252.

17. Siegel AB, Goldenberg DM, Cesano A, Coleman M, **Leonard JP**. CD22-directed monoclonal antibody therapy for lymphoma, Semin Oncol, 2003; 30(4):457-464.

18. Carnahan J, Wang P, Kendall R, Chen C, Hu S, Boone T, Juan T, Talvenheimo J, Montestruque S, Sun J, Elliott G, Thomas J, Ferbas J, Kern B, Briddell R, **Leonard JP**, Cesano A. Epratuzumab, a humanized monoclonal antibody targeting CD22: characterization of *in vitro* properties, Clin Cancer Res, 2003; 9(10):3982S-3990S.

19. Navolanic PM, Pui CH, Larson RA, Bishop MR, Pearce TE, Cairo MS, Goldman SC, Jeha SC, Shanholtz CB, **Leonard JP**, McCubrey JA. Elitek™-rasburicase: an effective means to prevent and treat hyperuricemia associated with tumor lysis syndrome, a meeting report, Dallas TX, January 2002, Leukemia 2003, 17(3):499-514.

20. **Leonard JP**, Coleman M, Ketas JC, Chadburn A, Ely S, Furman RR, Wegener WA, Hansen HJ, Ziccardi H, Eschenberg M, Gayko U, Cesano A, Goldenberg DM. Phase I/II trial of epratuzumab (humanized anti-CD22 antibody) in indolent non-Hodgkin's lymphoma, J Clin Oncol, 2003:21(16):3041-3059 (published with editorial comment).

21. Coleman M, Goldenberg DM, Siegel AB, Ketas JC, Fiore JM, **Leonard JP**. Epratuzumab: Targeting B-cell malignancies through CD22, Clin Cancer Res, 2003;9(10):2991S-3994S.

22. Furman RR, Coleman M, **Leonard JP**. Epratuzumab in non-Hodgkin's Lymphoma. Curr Treat Options Oncol. 2004;5(4):283-8.

23. Kostakoglu L, **Leonard JP**, Coleman M, Goldsmith SJ. The role of FDG-PET in the management of lymphoma. Clin Adv Hematol Oncol. 2004;2:115-121.

24. **Leonard JP**, Coleman M, Ketas JC, Chadburn A, Furman R, Schuster MW, Feldman EJ, Ashe M, Schuster SJ, Wegener WA, Hansen HJ, Ziccardi H, Eschenberg M, Gayko U, Fields SZ, Cesano A, Goldenberg DM. Epratuzumab (humanized anti-CD22 antibody) in aggressive non-Hodgkin's lymphoma: Phase I/II clinical trial results, Clin Cancer Res, 2004 (10), 5627-34 (published with editorial comment).

25. Davis TA, Kaminski MS, **Leonard JP**, Hsu FJ, Wilkinson M, Zelenetz A, Wahl R, Kroll S, Coleman M, Goris M, Levy R, Knox S. The radioisotope contributes significantly to the activity of radioimmunotherapy. Clin Cancer Res, 2004 (10), 7792-8.

26. Kostakoglu L, **Leonard JP**, Coleman M, Goldsmith SJ. The role of FDG-PET in the management of lymphoma. Clin Adv Hematol Oncol. 2004;2(2):115-21.

27. Bennett JM, Kaminski MS, **Leonard JP**, Vose JM, Zelenetz AD, Knox SJ, Horning S, Press OW, Radford JA, Kroll SM, Capizzi RL. Assessment of treatment-related myelodysplastic syndromes and acute myeloid leukemia in patients with non-Hodgkin's lymphoma treated with tositumomab and Iodine I 131 tositumomab (Bexxar). Blood, 2005 (12):4576-82.

28. Czuczman MS, Thall A, Witzig TE, Vose JM, Younes A, Emmanouilides C, Miller TP, Moore JO, **Leonard JP**, Gordon LI, Sweetenham J, Alkuzweny B, Finucane DM, Leigh BR. A phase I/II study of Galiximab, an anti-CD80 antibody, for relapsed or refractory follicular lymphoma. J Clin Oncol, 2005;23(19):4390-8.

29. **Leonard JP**, Coleman M, Ketas J, Ashe M, Fiore JM, Furman R, Niesvizky R, Shore T, Chadburn A, Horne H, Kovacs J, Ding CL, Wegener WL, Horak ID, Goldenberg DM. Combination antibody therapy with epratuzumab (humanized anti-CD22 antibody) and rituximab (chimeric anti-CD20 antibody) in relapsed/ refractory non-Hodgkin's lymphoma (NHL). J Clin Oncol, 2005:23(22):5044-51.

30. **Leonard JP**, Coleman M, Kostakoglu L, Chadburn A, Cesarman E, Furman R, Schuster MW, Muss D, Fiore J, Kroll S, Tidmarsh G, Vallabhajosula S, Goldsmith SJ. Abbreviated chemotherapy with fludarabine followed by Bexxar (tositumomab and Iodine I 131 tositumomab) for untreated follicular lymphoma. J Clin Oncol, 2005:23(24):5696-704.

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33. **Leonard JP**, Furman RR, Ruan J, Coleman M. New developments in immunotherapy for non-Hodgkin's lymphoma. Curr Oncol Rep, 2005;7(5):364-71.

34. **Leonard JP**. Targeting CD20 in follicular NHL: Novel anti-CD20 therapies, antibody engineering, and the use of radioimmunoconjugates, Hematology (Am Soc Hematol Educ Program), 2005;335-9.

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48. Roboz GJ, Bennett JM, Coleman M, Ritchie EK, Rossi A, Jhaveri K, Feldman EJ, **Leonard JP**. Myelodysplastic syndrome and acute myeloid leukemia Following initial treatment with chemotherapy plus radioimmunotherapy for indolent non-Hodgkin lymphoma, Leukemia Research, in press.

49. **Leonard JP** and Goldenberg DM. Preclinical and clinical evaluation of epratuzumab (anti-CD22 IgG) in B cell malignancies, Oncogene, in press.

50. Martin P, Furman R, Coleman M, **Leonard JP**. Phase I-III studies of anti-B cell therapy in non-Hodgkin's lymphoma, Clinical Cancer Research, in press.

51. **Leonard JP**, Friedberg JW, Younes A, Fisher D, Gordon LI, Moore J, Czuczman M, Miller T, Stiff P, Cheson BD, Forero-Torres A, Chieffo N, McKinney B, Finucane D, Molina A. A phase I/II study of galiximab (an anti-CD80 monoclonal antibody) in combination with rituximab for relapsed or refractory, follicular lymphoma, Annals of Oncology, accepted pending minor revision.

52. Niesvizky R, Christos PJ, Jayabalan DS, Furst JR, Cho HJ, Pearse RN, Zafar F, Pekle K, Lent R, Ely S, Jin DK, Shore T, Tepler J, Harpel J, Schuster M, Mathew S, **Leonard JP**, Rafii S, Chen-Kiang S, Mazumdar M, Coleman M. BiRD (Biaxin [clarithromycin]/Revlimid [lenalidomide]/Dexamethasone) combination therapy results in high complete and overall response rates in treatment-naïve symptomatic multiple myeloma patients, submitted.

53. Gregory SA, Zelenetz AD, Knox SJ, Vose JM, **Leonard JP**, Kaminski MS. Tositumomab and Iodine I 131 tositumomab in elderly patients with relapsed or refractory indolent or transformed non-Hodgkin's lymphoma, submitted.

54. Weng W and **Leonard JP**. Personalized active immunotherapy for non-Hodgkin's lymphoma: Mechanisms of efficacy, submitted.

55. Bartlett N, Younes A, Carabasi M, Forero A, Rosenblatt J, **Leonard JP**, Bernstein S, Bociek RG, Barton J. A phase I multi-dose study of SGN-30 immunotherapy in patients with refractory or recurrent CD30+ hematologic malignancies, submitted.

56. **Leonard JP**, Emmanouilides C, Gregory SA, Weisdorf D, Andrey J, Hainsworth J, Link B, Sparano J, Tsai D, Horning SJ, Kurman M, Krieg AM and Weiner GJ. A phase I trial of TLR9 agonist PF-3512676 (CpG 7909) in Relapsed or refractory non-Hodgkin's lymphoma patients with or after Rituximab, submitted.

Editorials, Books, Book Chapters

1. **Leonard JP** and Coleman M. Primary non-Hodgkin's lymphoma of bone. Cancer Invest, 1998;16:616-617.

2. **Leonard JP**. Epratuzumab (hLL2, anti-CD22) immunotherapy of non-Hodgkin's lymphoma. Hematologica, 2001, 86(S1):80-83.

3. **Leonard JP**. Extended duration neutrophil support for patients undergoing myelosuppressive chemotherapy. Curr Hematol Rep 2002 1(2), 93-94.

4. **Leonard JP** and Silverstein RL. "Corticosteroids in hematologic diseases". Chapter 28 in Principles of Corticosteroid Therapy, eds. Lin AN and Paget S. Chapman and Hall, 2002, New York, NY.

5. **Leonard JP**, Petryk M, Grossbard ML. "Monoclonal antibody therapy of lymphoma". Chapter 18 in American Cancer Society Atlas of Clinical Oncology, Malignant Lymphomas, ed. Grossbard ML, 2002. BC Decker.

6. **Leonard JP** and Coleman M. "Non-Hodgkin's Lymphoma", Conn's Current Therapy, ed. Rakel RE, 2002, Lippincott Williams and Wilkins, Philadelphia.514.

7. **Leonard JP**. "The 'FLIPI' is no 'FLOPI' ". Blood 2004, 104: 1233-1234.

8. **Leonard JP** and Coleman M, eds, Hodgkin's and Non-Hodgkin's Lymphoma, 2006, Springer

9. Siegel AB and **Leonard JP**. "Therapy for older patients with diffuse large cell lymphoma: Targeting the treatment to the patient". Leukemia and Lymphoma, in press.

10. Furman RR, **Leonard JP**, Decter J, Coleman, M. "Monoclonal antibodies in lymphoma", Gewirtz M, ed, Apoptosis and Senescence in Oncology, in press.

Selected Abstracts: (First-authored, oral abstract presentations at selected meetings)

1. **Leonard, JP,** Coleman M, Chadburn A, Matthews JC, Bayer R., Schuster, MW, Feldman EJ, Juweid M, Schuster SJ, Wegener WA, Goldenberg DM. Epratuzumab (HLL2, anti-CD22 humanized monoclonal antibody) is an active and well-tolerated therapy for refractory/relapsed diffuse large B-cell non-Hodgkin's lymphoma (NHL). Blood 96: 578a, 2000. Oral presentation at 2000 meeting of the American Society of Hematology.

2. **Leonard JP**, Coleman M, Kostakoglu L, Chadburn A, Cesarman E, Hack S, Kroll SM, Tidmarsh G, Vallabhajosula S, Goldsmith SJ. Triple modality therapy for follicular low-grade lymphoma: Initial treatment with fludarabine followed by Bexxar™ (tositumomab and Iodine I 131 tositumomab). Blood 98:3505, 2001. Oral presentation at 2001 meeting of the American Society of Hematology.

3. **Leonard JP**, Coleman M, Matthews JC, Fiore JM, Dosik A, Kapushoc H, Kin E, Cesano A, Wegener WA, Goldenberg DM. Combination monoclonal antibody therapy for lymphoma: Treatment with epratuzumab (anti-CD22) and rituximab (Anti-CD20) is well tolerated. Blood 98:3506, 2001. Oral presentation at 2001 meeting of the American Society of Hematology.

4. **Leonard JP**, Coleman M, Vose J, Hainsworth JD, Piro L, Saleh M, Bernstein S, Forero-Torres A, Frankel SR, Itri LM. Phase II study of oblimersen sodium (G3139, Bcl-2 antisense) alone and with R-CHOP in mantle cell lymphoma (MCL). Proceedings of the American Society of Clinical Oncology 22:566, 2003. Oral presentation at 2003 meeting of the American Society of Clinical Oncology.

5. **Leonard JP**, Vose J, Timmerman J, Levy R, Coleman M, King S, Ingolia D, Denney D. Recombinant idiotype-KLH vaccination (MyVax) following CHOP chemotherapy in mantle cell lymphoma. Blood 2003. Oral presentation at 2003 meeting of the American Society of Hematology.

6. **Leonard JP**, Hainsworth J, Bernstein S, Forero-Torres A, Vose J, Piro L, Saleh M, Coleman M, Frankel S, Smith S, Itri L. Genasense (Oblimersen sodium, G3139) is active and well tolerated both alone and with R-CHOP in mantle cell lymphoma (MCL). Blood 2003. Oral presentation at 2003 meeting of the American Society of Hematology.

7. **Leonard JP**, Zelenetz AD, Vose JM, Kaminski MS. Tositumomab and iodine I 131 tositumomab (the Bexxar therapeutic regimen) produces higher response rates and longer response durations than prior chemotherapy. Blood 2004. Oral presentation at 2004 meeting of the American Society of Hematology.

8. **Leonard JP**, Coleman MS, Link BK, et al. FLIPI predicts outcome in 65 patients with previously untreated indolent NHL who received bexxar in combination with chemotherapy. Ann Oncol 2005. Oral presentation at 9th International Conference on Malignant Lymphoma, Lugano Switzerland 2005.

9. **Leonard JP**, Friedberg J, Younes A, et al Results from a phase I/II study of galiximab (anti-CD80) in combination with rituximab (anti-CD20) for a relapsed or refractory, follicular NHL. Ann Oncol 2005. Oral presentation at 9th International Conference on Malignant Lymphoma, Lugano Switzerland 2005.

10. **Leonard JP**, Furman RR, Cheung YK, et al. Phase I/II trial of bortezomib + CHOP-rituximab in diffuse large B cell (DLBCL) and mantle cell lymphoma (MCL): Phase I results. Blood 2005. Oral presentation at 2005 meeting of the American Society of Hematology.

Presentations/Invited Lectures: (Selected regional, national and international meetings)

2000 "Novel immunotherapeutic strategies for low- and intermediate-grade non-Hodgkin's lymphoma", Novel Cytokine and Therapeutic Strategies, Super Friday Symposium, American Society of Hematology annual meeting, San Francisco, CA

2000 "Iodine I-131 tositumomab as upfront therapy for NHL", Managing Non-Hodgkin's Lymphoma in the New Millenium, Super Friday Symposium, American Society of Hematology annual meeting, San Francisco, CA

2001 "Iodine-131 tositumomab and chemotherapy as NHL therapy", Winter Oncology Conference, Whistler, British Columbia, Canada

2001 "Targeting CD22 in patients with relapsed NHL", First International Congress on Monoclonal Antibodies in Cancer, Banff, Alberta Canada

2001 "What is the advantage of the new monoclonal anti-CD22 antibody?", Lymphoma…the next questions symposium, Washington, D.C.

2001 "CD22-directed immunotherapy of lymphoma", Society for Biological Therapy 16th Annual Meeting, Bethesda, MD

2001 "Indolent lymphomas – Epratuzumab", New Drugs in Hematologic Malignancies symposium, Bologna, Italy

2001 "Alternative targets for immunotherapy – targeting CD22 with monoclonal antibodies for the treatment of non-Hodgkin's lymphoma", Super Friday Symposium, American Society of Hematology annual meeting, Orlando, FL

2001 "Monoclonal antibodies as single agents for non-Hodgkin's lymphoma", Education Session, American Society of Hematology annual meeting, Orlando, FL

2002 "Epratuzumab and other novel monoclonal antibodies for Lymphoma", Winter Oncology Conference, Whistler, British Columbia, Canada

2002 "Monoclonal antibodies for non-Hodgkin's lymphoma", invited speaker, AIDS Malignancy Consortium, National Cancer Institute, National Institutes of Health, Bethesda MD

2002 "Epratuzumab (anti-CD22) immunotherapy for NHL", Second International Congress on Monoclonal Antibodies in Cancer, Banff, Alberta, Canada

2002 "Iodine-131 labeled anti-B1 antibody for NHL", Second International Congress on Monoclonal Antibodies in Cancer, Banff, Alberta, Canada

2002 "Epratuzumab (anti-CD22) therapy for B cell malignancies", Conference on "Innovative therapies for lymphoid malignancies", Palermo, Italy

2002 "Radioimmunotherapy of non-Hodgkin's lymphoma", Chemotherapy Foundation Symposium XXI, New York, NY

2002 "Idiotype vaccination for NHL", Chemotherapy Foundation Symposium XXI, New York, NY

2002 "Targeting CD22 as immunotherapy for Non-Hodgkin's Lymphoma", Super Friday Symposium, American Society of Hematology Annual Meeting, Philadelphia PA

2003 "New developments in immunotherapy for non-Hodgkin's lymphoma", 9th Aichi Cancer Center International Symposium, Nagoya, Japan

2003 "Radioimmunotherapy of lymphoma", Society of Nuclear Medicine Mid-Winter Educational Symposium, Hollywood, FL

2003 "Epratuzumab and other novel monoclonal antibodies for NHL", Winter Oncology Conference, Whistler, British Columbia, Canada

2003 "Epratuzumab in the treatment of B-NHL", First International Symposium on Childhood and Adolescent Non-Hodgkin's Lymphoma, New York, NY

2003 "New developments in radioimmunotherapy for lymphoma", Pediatric Grand Rounds, Memorial Sloan-Kettering Cancer Center, New York NY

2003 "Monoclonal antibodies", invited speaker, State of the Science Symposium on Acute Lymphoblastic Leukemia, National Cancer Institute, Bethesda, MD

2003 "Vaccine and other novel therapies for NHL", Lymphoma…the next questions symposium, San Juan, Puerto Rico

2003 "Anti-CD22 monoclonal antibody – where will it fit in the management of lymphoma?", Lymphoma…the next questions symposium, San Juan, Puerto Rico

2003 "New developments in immunotherapy for lymphoma", Hematologic Oncology Grand Rounds, Memorial Sloan-Kettering Cancer Center, New York, NY

2003 "Epratuzumab", invited speaker, Pan-Pacific Lymphoma Conference, Kona HI

2003 "Future developments in antibody therapy of lymphoma", invited speaker, Conference on Post-Transplant Lymphoproliferative Disorders, National Institutes of Health, Bethesda MD

2003 "Initial therapy of NHL", Emerging therapies in hematologic malignancies symposium, Super Friday Symposium, American Society of Hematology annual meeting, San Diego CA

2004 Invited discussant, "Radioimmunotherapy. Where should we use it? Why don't we use it?". Nuclear Medicine Section, New York Academy of Medicine, New York NY

2004 "Epratuzumab", Winter Oncology Conference, Whistler, British Columbia, Canada

2004 "Idiotype vaccines for NHL", Winter Oncology Conference, Whistler, British Columbia, Canada

2004 "New developments in immunotherapy of B cell malignancies", invited speaker, Children's Oncology Group meeting, Washington, D.C.

2004 "New developments in radioimmunotherapy of lymphoma", Hematology/Oncology Grand Rounds, SUNY – Stony Brook, NY

2004 "New developments in immunotherapy of B cell malignancies", Leukemia Grand Rounds, MD Anderson Cancer Center, Houston TX

2004 "Novel approaches for the treatment of NHL", Lymphoma/Myeloma Grand Rounds, MD Anderson Cancer Center, Houston TX

2004 "New developments in immunotherapy of B cell malignancies", Lymphoma Conference, Johns Hopkins Oncology Center

2004 Invited discussant, "Rituximab in initial therapy for NHL", Hematologic malignancies oral presentation session, American Society of Clinical Oncology annual meeting, New Orleans LA

2004 "New developments in radioimmunotherapy for lymphoma", Hematology/Oncology Grand Rounds, Moffitt Cancer Center, Tampa FL

2004 "CD22-directed immunotherapy for lymphoma", Fourth International Congress on Monoclonal Antibodies in Cancer, Colorado Springs, CO

2004 "Epratuzumab", "Tenth anniversary of the REAL Classification – Open Issues" conference, invited speaker, Bologna Italy

2004 "Novel antibody combinations for lymphoma", Lymphoma/Myeloma 2004, NY NY

2004 "New developments in radioimmunotherapy for lymphoma", Medical Grand Rounds, Roswell Park Cancer Institute, Buffalo NY

2004 "Initial therapy of NHL", Emerging therapies in hematologic malignancies symposium, Super Friday Symposium, American Society of Hematology annual meeting, San Diego CA

2005 "New developments in lymphoma therapy", Hematology/Oncology Grand Rounds, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx NY

2005 "New developments in immunotherapy for NHL", Hematology/ Oncology Research Conference, Mount Sinai School of Medicine, New York, NY

2005 "New developments in radioimmunotherapy for lymphoma", Winter Oncology Conference, Whistler, British Columbia, Canada

2005 "Mantle cell lymphoma", Winter Oncology Conference, Whistler, British Columbia, Canada

2005 "New developments in lymphoma therapy: Can we get rid of chemotherapy?", Medical Grand Rounds, Weill Medical College of Cornell University, New York Presbyterian Hospital

2005 "Epratuzumab in aggressive NHL", Lymphoma…the next questions conference, Fort Lauderdale FL

2005 "New developments in lymphoma therapy", Hematology/Oncology Grand Rounds, University of Rochester School of Medicine

2005 "Novel strategies to enhance chemoimmunotherapy for NHL", Section of Hematology/Oncology, University of Nebraska Medical Center

2005 "Follicular Lymphoma", invited discussant, American Society of Clinical Oncology annual meeting, Orlando FL.

2005 Symposium chair, "Radioimmunotherapy: Why should we use it? Why don't we use it?", Pan Pacific Lymphoma Conference, Lihue, HI

2005 "Proteosome inhibition in aggressive lymphoma", Pan Pacific Lymphoma Conference, Lihue, HI

2005 "Radioimmunotherapy for lymphoma", Fifth International Congress on Monoclonal Antibodies in Cancer, Quebec City, Canada

2005 "New developments in lymphoma: can we get rid of chemotherapy?", Columbia University College of Physicians and Surgeons, NY

2005 "Treatment of the elderly patient with indolent lymphoma", Geriatric Oncology Consortium meeting, Washington DC

2005 "Idiotype vaccination for NHL", Chemotherapy Foundation Symposium, New York NY

2005 "Epratuzumab" and "Iodine-131 tositumomab", New drugs in hematologic malignancies meeting, Bologna Italy

2005 Invited speaker, American Society of Clinical Oncology, Medical Oncology Knowledge Workshop, Reston VA

2005 "Idiotype vaccination for aggressive lymphoma", Super Friday Symposium, American Society of Hematology annual meeting, Atlanta GA

2005 Invited speaker, education session, Targeting CD20 in follicular NHL: Novel anti-CD20 therapies, antibody engineering, and the use of radioimmunoconjugates, American Society of Hematology annual meeting, Atlanta GA

2006 "New developments in lymphoma therapy", Hematology/Oncology Grand Rounds, Rush University Medical Center, Chicago IL

2006 "New developments in Y-90 ibritumomab tiuexetan radioimmunotherapy for lymphoma", Winter Oncology Conference, Whistler, British Columbia, Canada

2006 "Risk-adapted initial therapy for follicular lymphoma", Winter Oncology Conference, Whistler, British Columbia, Canada

2006 "New developments in lymphoma therapy", Hematology/Oncology Grand Rounds, Beth Israel Medical Center/St. Lukes-Roosevelt Medical Center, New York, New York

2006 "New developments in antibody therapy: beyond rituximab", Second International Conference on Childhood NHL, New York, NY

2006 "Optimizing treatment options for low-grade lymphoma", CME symposium "Novel target therapies in hematologic malignancies: expanding efficacy and applications", 2006 annual meeting of the American Society of Clinical Oncology, Atlanta GA.

2006 "Monoclonal antibodies in hematologic malignancies", 8th International Congress on Biological Therapy of Cancer" (BDA/ESMO/NCI), Dresden, Germany.

2006 "High-risk asymptomatic follicular lymphoma patients should receive immediate therapy" (debate), Southern Association of Oncology Annual Meeting, Ponte Vedra, FL

2006 "Mantle cell lymphoma", American Society of Hematology State of the Art Symposium, Las Vegas NV

2006 "New developments in lymphoma therapy", Hematology/Oncology Grand Rounds, University of Virginia School of Medicine, Charlottesville, VA

2006 "New developments in radioimmunotherapy of lymphoma", Japanese Society of Hematology/Japanese Society of Clinical Hematology, Fukuoka, Japan

2006 "Recent progress in antibody therapy for lymphoma", Eleventh Conference on Cancer Therapy and Immunoconjugates, Parsippany, NJ

2006 "Radioimmunotherapy for indolent lymphoma", Lymphoma and Myeloma 2006, New York, NY

2006 "New developments in lymphoma therapy", Piedmont Oncology Association, Charleston SC

2006 "Pixantrone", Chemotherapy Foundation Symposium, New York, NY

2006 "Radioimmunotherapy in aggressive lymphoma", Lymphoma in the 21st century, Institute of Hematology and Oncology, University of Barcelona, Spain